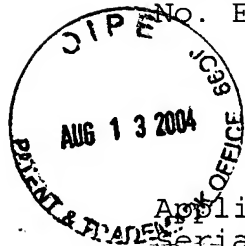


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PHA 4200.1  
C-3090  
PATENT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of John S. Ng, et al.

Art Unit 1616

Serial No. 10/672,680

Filed September 26, 2003

Confirmation No. 9809

For PROCESSES AND PREPARATION OF 9,11-EPOXY  
STERIODS AND INTERMEDIATES USEFUL THEREIN

Examiner B. Badio

August 13, 2004

LETTER TO THE PATENT AND TRADEMARK OFFICE

TO THE ASSISTANT COMMISSIONER FOR PATENTS,

SIR:

This is in response to the Office action dated May 14, 2004. Reconsideration of the restriction requirement is respectfully requested.

Many of the claims that are separately grouped in accordance with the restriction requirement have at least one prominent feature in common, and often share a number of features, so that they could be properly combined for searching and examination without undue burden on the Office. In addition, all of the separately grouped claims have been commonly classified in one of two classes.

It is respectfully submitted that the multiple splintering of closely related claims will be prejudicial to Applicants' assignee. The multiple divisional applications required to protect the claimed subject matter will impose excessive expense and consume scarce manpower resources in prosecuting closely related cases. For reasons also set forth below, it is respectfully submitted that dividing the application in accordance with the instant restriction requirement will not be in the public interest either.

All the claims are directed to intermediates in the reaction steps described in schemes for the preparation of eplerenone or eplerenone derivatives of Formula I. More particularly, each

claim is directed to intermediates in process Schemes 3-6 as described in the specification, in which eplerenone or a derivative thereof is ultimately prepared. Many of these intermediates share distinctive structural features.

It is respectfully submitted that splintering the claims of this application into nine separate inventions is unreasonable, will result in wasteful duplication of effort, cause Applicants' assignee to incur untoward expense, and impose an unwarranted burden on Applicants' manpower resources. It would seem to effect a similar burden on the resources of the Office.

Applicants therefore respectfully request that the claims be regrouped so that all compounds having a particular distinctive structural feature be examined in a single group, as outlined in the following table.

Common Feature	Class 540 (6+)	Class 552 (612+)
3,4(7)-diketone-5 $\beta$ -CN (schemes 3, 4)	I, II	
3-keto- $\Delta^{4,6}$ (schemes 4, 5)	III, IV	
3-alkoxy-11 $\alpha$ -OH- $\Delta^{3,5}$ (6) (scheme 6)	V, VI	VII

Thus, referring to the table above, Applicants respectfully request that the claims be regrouped as follows:

1. Claims 66-68 (Group I) and 69-71 (Group II) are directed to a family of diketone compounds, useful as key intermediates in the processes of Schemes 3 and 4. The combination of the keto groups at the 3 and 4,7 positions is a highly distinctive structural feature, which necessarily will be present in any prior art compound that can reasonably form the basis for rejection of any claim of Groups I or II. Likewise, the 5 $\beta$ -cyano group will necessarily be present in a relevant prior art compound. While the claims of

Groups I and II are indeed patentably distinct, the common need to find and apply art showing the diketone and 5 $\beta$ -cyano structure should reasonably confine the scope of the search and examination of the claims of these four groups.

2. Claims 72-74 (Group III) and 75-83 (Group IV) are directed to compounds having another highly distinctive structural feature, i.e., a 3-keto group with double bonds at the 4 and 6 positions. Not only do the Group III and IV claims all require the 3-keto- $\Delta^{4,6}$  feature, but all are in the same class, i.e., class 540. Thus, it is respectfully submitted that these claims should also be combined into a single group for examination.
3. Similarly, each of claims 84-94 (Group V), 95-99 (Group VI) and 100-104 (Group VII) are directed to compounds having a 3-alkoxy-11 $\alpha$ -OH- $\Delta^{3,5}$  structure. In addition, all of the compounds have a spirolactone group or a precursor thereof at the 17 position. These compounds also all serve as intermediates in the process of Scheme 6.

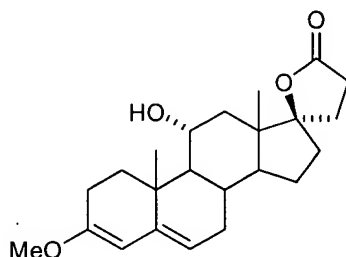
Still further supporting the proposed regrouping is the fact that all of the claims are encompassed in only two search classes.

Furthermore, it is respectfully submitted that multiple splitting of the claims in accordance with the instant restriction requirement will serve no ultimate purpose so far as the Office is concerned, but will only create needless and excessive expense on Applicants' part, and will require the Office to process a large number of parallel divisional applications with wasted duplication of labor. Those skilled in the art will be required to locate and review multiple patents containing the same specification in order to evaluate freedom to operate issues relating to a single process scheme, and/or patentability of improvements thereon. It is respectfully submitted that this is not in the public interest, and, as noted,

in the end it is not believed to create any saving in resources of the Office.

Election

Applicants provisionally elect the claims of Group V (claims 84-94) for examination in this application and elect, with traverse, the species of claim 87, i.e., the following structure

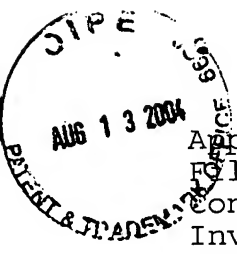


Enclosed is a check in the amount of \$420.00 in payment of the two-month extension. If there are any additional charges in this matter, please charge Deposit Account No. 19-1345.

Respectfully submitted,

John K. Roedel, Jr.

JSH/JKR/skd



FEE TRANSMITTAL

Application Number 10/672,680  
Filing Date September 26, 2003  
Confirmation No. 9809  
Inventor(s) John S. Ng, et al.  
Group Art Unit 1616  
Examiner Name B. Badio  
Attorney Docket Number PHA 4200.1

**METHOD OF PAYMENT**

1. ☐ The Commissioner is hereby authorized to charge the indicated fees to Deposit Account No. 19-1345.  
☐ The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17 to Deposit Account No. 19-1345.  
☐ Applicant claims small entity status.
2. ☒ Check Enclosed. The Commissioner is hereby authorized to charge any under payment or credit any over payment to Deposit Account No. 19-1345.

**FEE CALCULATION**

1. ☐ BASIC FILING FEE Subtotal (1) \$ \_\_\_\_\_  
(Type: \_\_\_\_\_)
2. ☐ EXTRA CLAIM FEES Subtotal (2) \$ \_\_\_\_\_  
Total Claims \_\_\_\_\_  
Independent Claims \_\_\_\_\_  
Multiple Dependent Claims \_\_\_\_\_
3. ☒ ADDITIONAL FEES Subtotal (3) \$ 420.00  
☐ Surcharge - late filing fee or oath  
☐ Surcharge - late provisional filing fee or cover sheet  
☒ Extension for reply within 2nd month  
☐ Notice of Appeal  
☐ Filing a Brief in Support of an appeal  
☐ Request for ex parte Reexamination  
☐ Petitions to the Commissioner  
☐ Submission of Information Disclosure Statement  
☐ Recording each patent assignment per property  
☐ Request for Continued Examination  
☐ Other: \_\_\_\_\_

**TOTAL AMOUNT OF PAYMENT** \$ 420.00

John K. Roedel, Jr.  
John K. Roedel, Jr., Reg. No. 25,914

August 13, 2004  
Date

JSH/JKR/skd

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